(e) Each application for approval shall contain a statement that the respirator and component parts submitted for approval are either prototypes, or made on regular production tooling, with no operation included which will not be incorporated in regular production processing.

(The information collections contained in this section are approved under OMB control number 0920–0109)

§ 84.12 Delivery of respirators and components by applicant; requirements.

(a) Each applicant shall, when an application is filed pursuant to § 84.10, be advised by the Institute of the total number of respirators and component parts required for testing.

(b) The applicant will deliver, at his or her own expense, the number of completely assembled respirators and component parts required for their examination, inspection, and testing, to the National Personal Protective Technology Laboratory.

(c) Respirators and component parts submitted for approval must be made from materials specified in the application.

(d) One completely assembled respirator approved under the provisions of this part may be retained by the Institute as a laboratory exhibit, the remaining respirators may be returned to the applicant at his own expense, upon written request within 30 days after notice of approval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

(e) Where a respirator fails to meet the requirements for approval set forth in this part, all respirators and components delivered in accordance with this section may be returned to the applicant at his own expense, upon written request within 30 days after notice of disapproval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

[60 FR 30355, June 8, 1995, as amended at 80 FR 3906, Jan. 26, 2015]

Subpart C—Fees

SOURCE: 80 FR 3906, Jan. 26, 2015, unless otherwise noted.

§ 84.20 Establishment of fees.

(a) This section establishes a system under which NIOSH charges a fee for services provided to applicants for conformity assessment activities conducted by NIOSH for respiratory protective devices under 42 CFR part 84. This section specifies the purposes for which fees will be assessed and the cost factors for such assessments.

(b) Fees will be charged for:

(1) *Respirator certification application, approval, approval modification, records maintenance, and testing.* Application processing under this Part by engineers, technicians and other specialists, including administrative review of applications, analysis of drawings, technical evaluation, testing, test set up and tear down, and consultation on applications, clerical services, computer tracking and status reporting, records control and security, and document preparation directly supporting application processing. This fee also contributes to a proportionate share of management, administration and operation of the NIOSH National Personal Protective Technology Laboratory;

(2) *Maintenance of testing and approval facilities and test equipment.* Amortization of facility improvements and depreciation of buildings and equipment used for testing and evaluation or otherwise directly associated with application processing;

(3) *Site qualification.* Initial review and approval, as specified under 42 CFR part 84 subpart E—Quality Control, of manufacturing facilities that may be used to manufacture respirators, principal components, and/or subassemblies;

(4) *Quality assurance maintenance.* Quality site audits to verify conformance to the requirements of §§ 84.33, 84.40, 84.41, 84.42, 84.43; and

(5) *Maintenance of product performance.* Product audits to verify the performance of commercially available respirators which have been granted a NIOSH certificate of approval.

(c) Fees will not be charged for:

(1) Technical assistance not related to application processing;

(2) Technical programs including development of new technology programs;

(3) Participation in research; and

(4) Regulatory review activities, including participation in the development of health and safety standards, regulations, and legislation.

§ 84.21 Fee calculation.

(a) This section explains the process NIOSH uses to calculate estimates of the direct and indirect costs of services provided in the course of application processing.

(b) Upon completion of an initial administrative review of the application, NIOSH will calculate a fee estimate for each application, including the maximum cost of conducting additional tests under § 84.24, and will provide that estimate, with payment details, to the applicant. The fee estimate will be derived using the current schedules of fees published by NIOSH in Part 84. NIOSH will begin the technical evaluation once the applicant accepts the terms of the fee estimate and authorizes payment.

(c) If NIOSH determines that actual costs for application processing and related testing will exceed the fee estimate provided to the applicant, NIOSH will provide a revised fee estimate for completing the application review before exceeding the previously-authorized fees. The applicant will have the option of either withdrawing the application and paying for services already performed or authorizing payment of the revised estimate, in which case NIOSH will continue the application review and testing.

(d) If the actual cost of processing the application is less than the fee estimate NIOSH provided to the applicant, NIOSH will charge the actual cost.

(e) If the applicant withdraws an application, the applicant will be invoiced for services already performed by NIOSH. Withdrawal of an application will be effective on the first business day following the date NIOSH receives a withdrawal notice from the applicant in writing. Withdrawal notices will be submitted to NIOSH in accordance with the *Standard Application Procedure* using the address specified in § 84.10.

§ 84.22 Fee administration.

(a) Applicants will be invoiced for all fees incurred in the processing of an application when all required reviews, analyses, evaluations, and tests are completed or the application is withdrawn. Invoices will contain specific payment instructions and identify authorized methods of payment.

(b) Applicants who hold active and/or obsolete certificates of approval will be invoiced by NIOSH annually for applicable maintenance fees, in accordance with the fee schedule published in Appendix A of this part.

(c) NIOSH reserves the right to impose sanctions for any missed payment, and will administer such penalties after assessing the circumstances of the manufacturer and the needs of other stakeholders. Sanctions may include but are not limited to:

(1) Refusal to accept future applications for approval;

(2) Stop-sale of all approved product; and

(3) Engaging appropriate government authorities to initiate debt collection procedures for the unpaid fees.

§ 84.23 Fee revision.

(a) Each fee schedule will remain in effect for at least 2 years and will be revised as needed to reflect cost increases identified in biennial reviews.

(b) Fee schedule updates will be proposed in a notice of proposed rulemaking published in the FEDERAL REGISTER.

(c) The current fee schedules will be published in Appendix A and Appendix B of this part and will remain in effect until the effective date of the new fee schedules published in the FEDERAL REGISTER.

§ 84.24 Authorization for additional examinations, inspections, tests, and fees.

NIOSH will conduct or cause to be conducted any additional examinations, inspections, or tests it deems necessary to determine the quality and effectiveness of any respirator submitted to NIOSH for the purposes of seeking a certificate of approval. The